Initial Approval Date: July 10, 2019

**CRITERIA FOR PRIOR AUTHORIZATION**

Plaque Psoriasis Agents

**BILLING CODE TYPE** For drug coverage and provider type information, see the KMAP Reference Codes webpage.

**MANUAL GUIDELINES** Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™)
Apremilast (Otezla®)
Brodalumab (Siliq™)
Certolizumab (Cimzia®)
Etanercept (Enbrel®, Erelzi™, Eticovo®)
Guselkumab (Tremfya®)
Infliximab (Remicade®, Reflexis™, Inflectra®, Ixifi™)
Ixekizumab (Taltz™)
Risankizumab (Skyrizi®)
Secukinumab (Cosentyx™)
Tildrakizumab (Ilumya™)
Ustekinumab (Stelara™)

**GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION:** (must meet all of the following)

- Must be approved for the indication, age, weight (if applicable), and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a dermatologist.[1,2]
- Patient must have had an adequate trial (at least 90 consecutive days within the past 120 days) of or contraindication to methotrexate.[3] If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.[3,8,14,15,16,17]
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of ONE of the following criteria:
    - Severe Plaque Psoriasis defined as one of the following: [1]
        - Body surface area (BSA) involvement ≥ 10%.
        - Location on hands, feet, scalp, face, or genital area.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Plaque Psoriasis Agents (PsO)[4-22]

| Medication | Indication(s) | Age | Dosing Limits |
|---|---|---|---|
| **Interleukin-12 and -23 Inhibitors** | | | |
| Ustekinumab (Stelara™) | PsO | ≥ 12 years | ≤ 100 kg: 45 mg initially SC at weeks 0 and 4, followed by 45 mg every 12 weeks thereafter.<br><br>> 100 kg: 45-90 mg initially SC at weeks 0 and 4, followed by 45-90 mg every 12 weeks thereafter. |
| **Interleukin-17a Inhibitors** | | | |
| Secukinumab (Cosentyx™) | PsO | ≥ 18 years | 150-300 mg SC once weekly at weeks 0, 1, 2, 3, and 4, followed by 150-300 mg every 4 weeks. |
| Ixekizumab (Taltz™) | PsO | ≥ 18 years | 160 mg initially SC, followed by 80 mg at weeks 2, 4, 6, 8, 10 and 12, followed by 80 mg every 4 weeks. |
| Brodalumab (Siliq™) | PsO | ≥ 18 years | 210 mg SC at 0, 1, and 2 weeks, followed by every 2 weeks. |
| **Interleukin-23 Inhibitors** | | | |
| Guselkumab (Tremfya®) | PsO | ≥ 18 years | 100 mg SC at 0 and 4 weeks, followed by every 8 weeks. |
| Risankizumab (Skyrizi™) | PsO | ≥ 18 years | 150 mg SC (given as two consecutive injections of 75 mg each) weeks 0 and 4 followed by 150 mg every 12 weeks. |
| Tildrakizumab (Ilumya™) | PsO | ≥ 18 years | 100 mg SC at 0 and 4 weeks, followed by every 12 weeks. |
| **Phosphodiesterase-4 Enzyme Inhibitor** | | | |
| Apremilast (Otezla®) | PsO | ≥ 18 years | 30 mg orally twice daily. |
| **Tumor Necrosis Factor-Alpha (TNF-α) Blockers** | | | |
| Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™) | PsO | ≥ 18 years | 80 mg initially SC on day 1, followed by 40 mg every other week beginning 1 week later (day 8). |
| Certolizumab (Cimzia®) | PsO | ≥ 18 years | 400 mg initially SC at weeks 0, 2, and 4 followed by 400 mg every other week. |
| Etanercept (Enbrel®) | PsO | ≥ 4 years | Pediatrics:<br>< 63 kg: 0.8 mg/kg SC once weekly, up to a maximum of 50 mg per dose.<br>≥ 63 kg: 50 mg SC once weekly.<br><br>Adults: 25-50 mg SC twice weekly for 3 months followed by 50 mg once weekly. |
| Etanercept-szzs (Erelzi™, Eticovo®) | PsO | ≥ 18 years | 25-50 mg SC twice weekly for 3 months followed by 50 mg once weekly. |
| Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™) | PsO | ≥ 18 years | 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks. |

SC: subcutaneous. IV: intravenous

**LENGTH OF APPROVAL (INITIAL):** 6 months

**CRITERIA FOR RENEWAL PRIOR AUTHORIZATION:** (must meet all of the following)

- Prescriber must provide at least ONE of the following response measure(s):
  - BSA improvement ≥ 75% compared to baseline.[2]
  - BSA involvement ≤ 3%.[2]
  - Resolved involvement on hands, feet, scalp, face, and/or genital area AND no new involvement in any of these areas.
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

**LENGTH OF APPROVAL (RENEWAL):** 12 months

**FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:**

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

**LENGTH OF APPROVAL (INITIAL AND RENEWAL):** 12 months

Table 2. List of conventional therapy in the treatment of PsO.[3]

| Conventional Psoriasis Therapy | |
|---|---|
| **Generic Name** | **Brand Name** |
| Acitretin | Soriatane® |
| Cyclosporine | Gengraf®, Neoral® |
| Methotrexate | Trexall®, Rheumatrex®, Otrexup®, Rasuvo® |

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

| Biologic Agents/Janus Kinase Inhibitors | | |
|---|---|---|
| Actemra® (tocilizumab) | Humira® (adalimumab) | Rituxan® (rituximab) |
| Amevive® (alefacept) | Hyrimoz™ (adalimumab-adaz) | Siliq® (brodalumab) |
| Amjevita™ (adalimumab-atto) | Ilaris® (canakinumab) | Simponi® (golimumab) |
| Cimzia® (certolizumab) | Ilumya™ (tildrakizumab-asmn) | Simponi Aria (golimumab) |
| Cinqair® (reslizumab) | Inflectra® (infliximab-dyyb) | Skyrizi™ (Risankizumab) |
| Cosentyx® (secukinumab) | Ixifi™ (infliximab-qbtx) | Stelara® (ustekinumab) |
| Cyltezo™ (adalimumab-adbm) | Kevzara® (sarilumab) | Taltz® (ixekizumab) |
| Dupixent® (benralizumab) | Kineret® (anakinra) | Tremfya® (guselkumab) |
| Enbrel® (etanercept) | Nucala® (mepolizumab) | Tysabri® (natalizumab) |
| Entyvio® (vedolizumab) | Olumiant® (baricitinib) | Xeljanz® (tofacitinib) |
| Erelzi™ (etanercept-szzs) | Orencia® (abatacept) | Xeljanz XR® (tofacitinib) |
| Eticovo® (etanercept-ykro) | Remicade® (infliximab) | Xolair® (omalizumab) |
| Fasenra™ (benralizumab) | Renflexis® (infliximab-abda) | |

References:

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3. Guidelines of care for the management of psoriasis and psoriatic arthritis Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. J Am Acad Dermatol 2011;65:137-74. Available at https://www.jaad.org/article/S0190-9622(10)02173-0/abstract. Accessed on 6/20/19.
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5. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.
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15. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; September 2018.
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17. Ixifi (infliximab-qbtx) [prescribing information]. Ringaskiddy, Co. Cork, Ireland: Pfizer Ireland Pharmaceuticals; December 2017.
18. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; May 2018.
19. Skyrizi (risankizumab) [prescribing information]. North Chicago, IL: AbbVie Inc; April 2019.
20. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2018.
21. Ilumya (tildrakizumab-asmn) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; August 2018.
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| DRUG UTILIZATION REVIEW COMMITTEE CHAIR | PHARMACY PROGRAM MANAGER<br>DIVISION OF HEALTH CARE FINANCE<br>KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT |
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